



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Jeffrey Thruston at 301-594-5179 or jeffrey.thruston@nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Alpha-Synuclein RT-QuIC: An Ultrasensitive Assay for the Detection of Alpha-Synuclein Seeding Activity Associated with Synucleinopathies

Description of Technology:

Synucleinopathies are a category of neurodegenerative diseases defined by the abnormal aggregation and accumulation of misfolded alpha-synuclein protein molecules within the brain. These aggregates are of particular concern to humans as they are a primary cause of Parkinson's disease, dementia with Lewy bodies, and other neurological disorders. This technology enables rapid, economical and ultrasensitive detection of disease-associated forms of alpha-synuclein as biomarkers or indicators of synucleinopathy in a biological sample. Specifically, alpha-synuclein aggregates (contained in a biological sample) seed the polymerization of vast stoichiometric excesses of recombinant, normally folded alpha-synuclein into amyloid fibrils that are then detectable by an amyloid-sensitive fluorescent dye. This reaction can thereby amplify the seeds in a biospecimen by many orders of magnitude. For example, in its current embodiment, this assay has been used to detect alpha-synuclein seeds in cerebral spinal fluid from living patients with Parkinson's disease and Lewy-body dementia, giving high diagnostic sensitivity and specificity with unprecedented speed.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- Pre-mortem diagnosis of synucleinopathies, including Parkinson's disease and Lewy-body dementia.

- A monitor of the disease progression of dementia and synucleinopathies
- Clinical trial / drug development companion diagnostic

Competitive Advantages:

- Uses a consistent, concentrated source of truncated alpha-synuclein protein substrate
- Capable of disease detection prior to onset of symptoms
- Rapid and economical

Development Stage:

- Research Use.

Inventors: Byron Caughey (NIAID), Bradley Groveman (NIAID), Christina Orru (NIAID), Lynne Raymond (NIAID)

Publications: Groveman, Bradley R et al. "Rapid and ultra-sensitive quantitation of disease-associated α -synuclein seeds in brain and cerebrospinal fluid by α Syn RT-QuIC." *Acta Neuropathologica Communications* vol. 6(1):7, 9 Feb. 2018.

Licensing Contact: To license this technology, please contact Jeffrey Thruston at 301-594-5179 or jeffrey.thruston@nih.gov, and reference E-233-2017-0.

Dated: February 25, 2020.

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Technology Transfer and Intellectual Property Office,

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